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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO.       |
|--|-------------|----------------------|-------------------------|------------------------|
| 10/804,502   | 03/19/2004  | Mary L. Cunningham   | 04289-00190-US          | 7682                   |
| 23416 7590 08/29/2007<br>CONNOLLY BOVE LODGE & HUTZ, LLP<br>P O BOX 2207<br>WILMINGTON, DE 19899 |             |                      | EXAMINER<br>OLSON, ERIC |                        |
|  |             |                      | ART UNIT<br>1623        | PAPER NUMBER           |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/804,502 | <b>Applicant(s)</b><br>CUNNINGHAM ET AL. |  |
|                              | <b>Examiner</b><br>Eric S. Olson     | <b>Art Unit</b><br>1623                  |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>July 9, 2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **Detailed Action**

This office action is a response to applicant's communication submitted July 9, 2007 wherein claims 1, 3, and 6-17 are amended. This application claims benefit of provisional application 60/456163, filed March 20, 2003.

Claims 1-20 are pending in this application.

Claims 1-20 as amended are examined on the merits herein.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 16, 2007 has been entered.

Applicant's arguments submitted July 9, 2007, with respect to the rejection of instant claims 2 and 18-19 under 35 USC 103(a) for being obvious over Lynch in view of Darsow, have been fully considered and found to be persuasive to remove the rejection as the cited references do not teach or fairly suggest the use of magnesium powder. Therefore the rejection is withdrawn.

The following rejections of record in the previous office action are maintained:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch (US patent 4471001, of record in previous action) Lynch discloses a composition comprising hydrogenated sugars including maltitol, sorbitol, and minor amounts of higher saccharides, and a process or preparing the same. (abstract) These syrups can contain 60-85% by weight solids. (column 3, line 55) The syrups have a solid content of 60-85% by weight in aqueous maltitol solution, which corresponds to a water content of 15-40%, encompassing the claimed 32-38% water content. (column 3, lines 60-68) Syrup obtained from hydrogenated maltose can have, on a dry weight basis, 25-29% maltitol, 2-30% sorbitol, and 0.05-2% reducing sugars and higher saccharides on a dry weight basis. (column 3, lines 55-59) It is noted that HP 3 and HP 4+ are defined as hydrogenated tri- and tetra- and greater saccharides of reducing sugars. (instant specification, p. 2, third paragraph) Therefore the prior art's 25-94% maltitol, 2-30% sorbitol, and 0.05-2% reducing sugars and higher saccharides on a dry weight basis encompass the maltitol solutions of the instant claims. A specific preparation is disclosed comprising 71-78% solids, consisting of 85.6-94.0% maltitol, 2-5% sorbitol, 2.1-2.6% higher saccharides, and 0.013-0.24% reducing sugars on a dry weight basis. (column 3, lines 5-13) The process used to produce these syrups involve

Art Unit: 1623

the hydrogenation of maltose-containing corn syrups followed by cation exchange and anion exchange, and concentration by evaporation. (column 2, lines 38-62) Lynch also discloses that in many cases a formulation with the desired appearance can be obtained only by varying the different ingredients until a suitable appearance, particularly a suitable refractive index, is obtained. (column 4, lines 10-17) The refractive index can also be adjusted by adding or subtracting water from a silica/maltitol syrup composition. (column 4, lines 25-29) In one example, the maltitol preparation I, which has a solids content of 70-85%, is diluted with 21% water and 10% silica, which would produce a solids content of about 58-69%, a range which encompasses the claimed solids content. (column 4, lines 58-68) Lynch does not disclose compositions comprising the exact amounts of each ingredient recited in the instant claims, particularly 94.6-99% maltitol.

It would have been obvious to one of ordinary skill in the art at the time of the invention to produce maltitol solutions having the exact amounts of each ingredient recited in the instant claims. Specifically, it would have been within the level of ordinary skill in the art to optimize the various ingredients through routine experimentation to arrive at the claimed invention, particularly because Lynch already discloses that such optimization is needed to adjust the appearance of the solution, particularly the refractive index, to the desired value. Because the claimed value is very close to the upper limit of 94% disclosed by Lynch, one of ordinary skill in the art would reasonably expect the claimed compositions to behave in a predictable manner as compared to the prior art compositions disclosed by Lynch.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted April 16, 2007, with respect to the above ground of rejection have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that Lynch does not disclose syrups having a maltitol content of over 94%. However, the maltitol content of the claimed syrups is extremely close to 94%, and is within the range of routine experimentation considering that Lynch already provides motivation for optimizing and modifying the composition of the syrups. With respect to Applicant's statement that, "there is no teaching in Lynch of how the properties of the syrup are changed by changes in the amount of maltitol," Lynch does disclose that the amounts of various components such as maltitol and sorbitol affect the refractive index of the syrup, which is a critical variable for the intended use of the syrup. Therefore one of ordinary skill in the art would in fact be motivated to test various concentrations of maltitol to optimize the refractive index, and would recognize that the maltitol content is a result effective variable.

Applicant also argues that Lynch teaches away from a syrup with less than 75% solids content. This is not the case because, as discussed above, Lynch discloses a clear stable gel base in example I in which the maltitol syrup of preparation I is diluted with water, leading to a composition with notably less than 75% solids. Therefore Lynch does in fact teach that the claimed syrups can be prepared as gel bases having less than 75% solids.

Applicant further claims that Lynch does not disclose which other ingredient can be subtracted to make room for the added maltitol. One of ordinary skill in the art would recognize that, from Lynch's teaching of "varying the ingredient concentrations," the other ingredients such as sorbitol or higher saccharides could be subtracted.

Applicant argues that claim 7 has been amended to recite a solution having a content of higher saccharides that is 0.1% lower than that disclosed in the lowest amount (preparation II) disclosed by Lynch. As discussed above with respect to the content of maltitol, the difference between the prior art and the instant claims is within the range of ordinary experimentation and optimization. Carrying out Lynch's guidelines for varying the ingredient concentrations and arriving at these particular formulations is the result not of innovation but of routine experimentation.

Finally, Applicant speculates that the composition of preparation II might contain less than 94% maltitol, based on calculations of the maximum amount of each ingredient present and the mass balance of preparation III. While preparation II can contain less than 94% maltitol, for example 88/5% maltitol, the ranges expressed also indicate that embodiments of preparation II can contain more than that, as much as 94% maltitol. The embodiment described in preparation II is clearly a range of possible concentrations, for example representing variation between different batches prepared by this method. One of ordinary skill in the art would realize that, in batches where the maltitol content was as high as 94%, the amounts of sorbitol and higher saccharides would be somewhat lower, for example 3.5% and 2.5 respectively. What this

embodiment does indicate is that Lynch directly contemplated maltitol solutions having as much as 94% maltitol.

For these reasons the rejection is maintained.

The following new grounds of rejection are introduced:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method involving a specific hydrogenation catalyst such as nickel or copper, does not reasonably provide enablement for a method involving any hydrogenation catalyst whatsoever. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl's 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims;



(6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a method of performing a chemical reaction, involving a catalyst. In order to practice a chemical reaction, one skilled in the art must be able to obtain each and every reactant, catalyst, solvent, or other ingredient used in the reaction.

The state of the prior art: Numerous catalysts are known in the art to catalyze the addition of hydrogen to an organic substrate. Among these are various metals such as palladium, platinum, ruthenium, nickel, and copper, as well as homogeneous inorganic complexes. The prior art does not disclose a full and exhaustive listing of each and every possible hydrogenation catalyst.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: The chemistry of inorganic compounds is more complex and less well understood than that of organic compounds. The discovery of novel catalysts often proceeds by trial and error, with limited foresight or prediction of which potential catalysts are useful for a particular reaction. Furthermore, in order to produce a particular compound, one skilled in the art must, if it is not commercially available, develop a synthetic scheme in order to produce it. While some synthetic schemes are simple, others are highly complex and involve a significant amount of trial and error before they are workable. Given the enormous amount of compounds that must be tested in order to practice the claimed invention with every

possible hydrogenation catalyst, the process of obtaining all such catalysts is highly unpredictable.

The Breadth of the claims: The claimed invention is extremely broad, including methods that involve any compound whatsoever that can catalyze the addition of hydrogen to a carbohydrate carbonyl group.

The amount of direction or guidance presented: Molybdenum-promoted Raney nickel catalysts are described in the specification as being useful in the claimed hydrogenation method. No guidance is provided for the discovery of novel hydrogenation catalysts.

The presence or absence of working examples: No working examples are provided for other catalysts besides Raney nickel catalysts.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the discovery of novel hydrogenation catalysts. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the full scope of the invention, one skilled in the art would have to catalog each and every possible hydrogenation catalyst. In order to do so, the skilled practitioner would have to test millions of possible compounds for potential catalytic activity. Obtaining all of these diverse and unrelated compounds would involve a laborious and unpredictable process of making each compound, since most of them are not readily available. This experimental program would therefore constitute undue and unpredictable experimentation.

*Genentech*, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims and the unpredictability of the art, Applicants fail to provide information sufficient to practice the claimed invention for all possible hydrogenation catalysts.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 18, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch (US patent 4471001, reference of record in previous action) as applied to claims 1 and 3-17 above, and further in view of Brudermüller et al. (US patent 6201160, cited in PTO-892) The disclosure of Lynch is discussed above. Lynch does not disclose a method of making maltitol solutions wherein the catalyst used includes magnesium as a reaction promoter.

Brudermüller et al. discloses a process for catalytic hydrogenation of carbonyl compounds at elevated temperatures and pressures in the presence of a copper/SiO<sub>2</sub> catalyst additionally containing a metal selected from several choices including magnesium. (column 2, lines 38-45) Hydrogenation is carried out at a preferred temperature of 80-160°C and 20-100 bar of hydrogen, which is 290-1450 psig. (column 5, lines 61-67) A variety of different aliphatic aldehydes can be hydrogenated to alcohols by this process. (column 8, lines 12-50)

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the method and catalyst of Brudermüller et al. for the one used by Lynch to prepare the hydrogenated syrup. One of ordinary skill in the art would have recognized that, because both processes are useful for hydrogenating aldehydes, such as aldoses, into alcohols, such as sugar alcohols, they can be used interchangeably. Substituting one equivalent prior art process for another is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch (US patent 4471001, reference of record in previous action) in view of Brudermüller et al. (US patent 6201160, cited in PTO-892) as applied to claims 2, 18, and 20 above, and further in view of Tasaki. (US patent 6060526, reference included with PTO-892) The disclosure of Lynch in view of Brudermüller et al. is discussed above. Lynch in view

of Brudermüller et al. does not disclose a purification step wherein the solution is purified with a mixed cation and anion exchange resin.

Tasaki et al. discloses a mixed-bed ion exchange resin that exchanges both cations and anions. (column 2, lines 3-15) These mixed bed resins are useful for deionization of aqueous solutions. (column 2, lines 17-35)

It would have been obvious to one of ordinary skill in the art to use the mixed bed ion exchange resins of Tasaki et al. to further purify the maltitol syrups of Lynch et al. One of ordinary skill in the art would have recognized that these syrups fall within the range of aqueous solutions that can be deionized using the ion exchange resins of Tasaki et al. In particular, Lynch et al. already discloses that the hydrogenated syrups should be purified by ion exchange. It is part of the ordinary and routine level of skill in the art to combine two prior art elements where the prior art provides a teaching that suggests their combination.

Therefore the invention taken as a whole is *prima facie* obvious.

### **Conclusion**

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

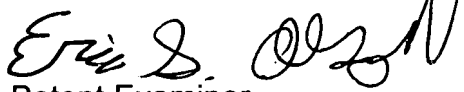
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone

Art Unit: 1623

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Olson



Patent Examiner

AU 1623

8/24/07

Anna Jiang



Supervisory Patent Examiner

AU 1623